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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/595,720	CHERONIS ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20050324*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 21 January 2005 is acknowledged and has been entered.

Claim Objections

2. Claim 5 is objected to because of the following informalities: the term "molecule" (line 1) seems like it should be "molecules". Appropriate correction is required.

3. Claim 45 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In claim 1, lines 4 and 13, the phrase "each target molecule" is vague and indefinite. Since the preamble states "assaying one or more target molecules in a first sample" (lines 1-2), which includes the situation wherein there is only one molecule, it is unclear how nucleic acid aptamer (lines 3-4) can be prepared for the instant phrase, which implies more than one target molecule, if there is just one target molecule in the first sample.

7. In claims 3-4, the phrases "at molar concentrations" (line 2) and "their dissociation constants" (lines 2-3) are vague and indefinite. Since the claims indicate that there is only one target molecule (line 1), it is unclear how there can be multiple molar concentrations and dissociation constants.

8. In claim 15, line 1, the phrase "the sample" is vague and indefinite. Which sample in claim 1 is the instant term referring to: the first sample or the second sample?

9. In claim 26, line 3, the term "the antibody" is vague and indefinite. Since there are multiple antibody molecules (line 2), which antibody does the instant term refer to?

10. In claim 28, line 2, the term "the antibody" is vague and indefinite. Since parent claims 24-26 recite multiple antibody molecules, which antibody does the instant term refer to?

11. In claim 30, line 5, the phrase "one of the target molecules" is vague and indefinite. Since the parent claim, claim 1, indicates that there may only be one target molecule (line 1), it is unclear as to how the instant claim can have multiple target molecules, as suggested by the instant phrase.

12. Claim 21 recites the limitation "measuring the amount of aptamer" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites the phrase "to determine a quantity of aptamer" (line 12), but there is no recitation of the instant limitation.

13. Claim 31 recites the limitation "each immobilized ligand" in line 6. There is insufficient antecedent basis for this limitation in the claim. Since lines 2-3 recite "an immobilized ligand", there is no antecedent basis for multiple ligands.

14. Claim 33 recites the limitation "the aptamer-binding characteristics" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claim 1-2, 5-8, 13-24, 33, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984).

Dodge et al reference teaches quantitating a target compound in a sample (i.e. quantitatively assaying one or more target molecules in a first sample) by placing a detector molecule in contact with a capture molecule:target molecule complex (i.e. adding to the first sample, a preparation specific for each target molecule) to form a capture molecule:target molecule:detector molecule ternary complex (i.e. allowing substantially all of the target molecules in the first sample to bind with the aptamer), wherein the detector molecule is a nucleic acid aptamer obtained from the SELEX method (i.e. nucleic acid aptamer), removing unbound detector molecule from the complex (i.e. separating unbound aptamer from the first sample, so as to recover a second sample of aptamer bound to target molecules), and performing real time PCR amplification of the detector molecule (i.e. using a quantitative replicative procedure comprising a replicative polymerase reaction to determine a quantity of aptamer specific for each target molecule in the second sample and therefore related to the concentration of target molecule in the first sample). See page 3, section 0018 ; page 6, section 0045; page 7, sections 0053-0058 ; and page 9, sections 0066-0067 and 0071.

However, Dodge et al reference fails to teach that the separating step requires contacting the sample of step (b) with immobilized ligands, thereby binding the ligands to unbound aptamer.

Freytag et al reference teaches the step of removing excess labeled monovalent antibody (i.e. preparation specific for each target molecule) such that only the labeled monovalent antibody that possess an antigen in its binding site elutes from the column

(i.e. so as to recover a second sample preparation bound to target molecules), in order to provide a separation step that increases the sensitivity limit, and provides an assay that is rapid and can easily be automated. See page 417, right column, 3rd paragraph; page 418, right column, 1st paragraph; and Figure 1 and caption. In addition, the step provides an alternative method of separating bound and unbound fractions of a sample.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Dodge et al the step of removing excess labeled monovalent antibody (i.e. preparation specific for each target molecule) such that only the labeled monovalent antibody that possess an antigen in its binding site elutes from the column (i.e. so as to recover a second sample preparation bound to target molecules), as taught by Freytag et al, in order to provide a separation step that increases the sensitivity limit, provides an assay that is rapid and can easily be automated, and is an alternative method of separating bound and unbound fractions of a sample. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of including the separation step of Freytag et al in the method of Dodge et al, since Dodge et al teach the separation of bound and unbound fractions by capturing unbound nucleic acid binding agents (see page 9, section 0066) and that affinity columns can be used to bind nucleic acids (see page 4, section 0020, line 7), and the separation step taught by Freytag et al also captures binding agents and uses an affinity column.

With regards to claim 2, Dodge et al teach a DNA oligonucleotide (i.e. single-stranded DNA). See page 9, section 0067.

With regards to claim 5, Freytag et al teach 10^{-14} mol of analyte (i.e. low abundance molecules). See page 417, right column, 3rd paragraph.

With regards to claims 6-8 and 13-17, Dodge et al teach protein and small organic targets (i.e. small organic molecule), that the targets are from blood or organ tissues in animal samples, or plant samples. See page 7, section 0059.

With regards to claims 18-19, Freytag et al teach an affinity column with resin. See page 418, left column, 2nd paragraph; and Figure 1 and caption.

With regards to claims 20-23, Dodge et al teach that the elevated temperatures which occur during standard PCR amplification reactions (i.e. quantitative polymerase chain reaction; oligonucleotide primers are added) are sufficient to release the detector molecule from the ternary complex for amplification (i.e. denaturing the aptamer so as to separate the nucleic acid from the target molecules), and also teach determining the cycle number where the fluorescence value crosses a threshold value (i.e. determining the number of replicative counts) in performing real time PCR, as stated above. See page 9, sections 0067 and 0071.

With regards to claim 24, Dodge et al teach that aptamers can bind to antibodies. See page 4, section 0022.

With regards to claim 33, Freytag et al teach that the unbound antibody is captured by antigen analogue (i.e. binding characteristics of the target molecule), as stated above.

19. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984) as applied to claim 1 above, and further in view of Patel et al (US 6,281,245 B1).

Dodge et al and Freytag et al references have been disclosed above, but fail to teach that the target molecule is present in the sample at molar concentrations less than or equal to their dissociation constants with respect to the aptamers.

Patel et al reference teaches a bioactive molecule (i.e. target molecule) with a solution concentration of 10^{-3} molar, and a dissociation constant of 10^{-3} molar or less with other biological macromolecules such as DNA and RNA (i.e. aptamer), in order to provide a molecule in a sample that has inhibitory activity. See column 24, lines 23-43.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Dodge et al and Freytag et al with a bioactive molecule (i.e. target molecule) with a solution concentration of 10^{-3} molar, and a dissociation constant of 10^{-3} molar or less with other biological macromolecules such as DNA and RNA (i.e. aptamer), as taught by Patel et al, in order to provide a molecule in a sample that has inhibitory activity. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the bioactive molecule of Patel et al in the method of Dodge et al and Freytag et al, since Dodge et al and Freytag et al teach target molecules that bind to DNA aptamers, and the bioactive molecule of Patel et al can bind to DNA.

20. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984) as applied to claims 1 and 8 above, and further in view of Wang et al (Biochemistry, vol. 35, pp. 12338-12346).

Dodge et al and Freytag et al references have been disclosed above, but fail to teach that target molecules are antibiotics.

Wang et al reference teaches aminoglycoside antibiotics that bind to RNA aptamer, in order to design aminoglycoside analogs specific for a particular RNA structure. See page 12338, left column, lines 12-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Dodge et al and Freytag et al with aminoglycoside antibiotics that bind to RNA aptamer, as taught by Wang et al, in order to design aminoglycoside analogs specific for a particular RNA structure. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including aminoglycoside antibiotics, as taught by Wang et al, in the method of Dodge et al and Freytag et al, since Dodge et al and Freytag et al teach aptamers that bind to small organic targets, and the antibiotic target taught by Wang et al bind to RNA aptamers and is one type of small organic target.

21. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no.

3, pp. 417-420, 1984) as applied to claim 1 above, and further in view of Mandal et al (Bioconjugate Chemistry, vol. 8, pp. 798-812, 1997).

Dodge et al and Freytag et al references have been disclosed above, but fail to teach that target molecules are metal complexes.

Mandal et al reference teaches the interactions of transition metal complexes with DNA, in order to aid in the design of drugs. See page 798, 1st column.

It would have been obvious to modify the method of Dodge et al and Freytag et al with interactions of transition metal complexes with DNA, as taught by Mandal et al, in order to aid in the design of drugs. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including metal complexes as target molecules, as taught by Mandal et al, in the method of Dodge et al and Freytag et al, since Dodge et al and Freytag et al teach oligonucleotides that bind to targets, and the metal complexes taught by Mandal et al bind to DNA, which are components in oligonucleotides.

22. Claims 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984) as applied to claims 1, 6, and 24 above, and further in view of Murray (US 3,957,436).

Dodge et al and Freytag et al references have been disclosed above, but fail to teach that the target molecules include IgE, and wherein the target molecules are a subclass of an antibody having a characteristic hypervariable region.

Murray reference teaches detecting IgE (i.e. IgE; subclass of an antibody having a characteristic hypervariable region), in order to determine high levels of IgE in serum that would indicate allergic diseases such as asthma, hay fever, and allergic rhinitis. See column 3, lines 14-20.

It would have been obvious to modify the method of Dodge et al and Freytag et al with detecting IgE (i.e. IgE; subclass of an antibody having a characteristic hypervariable region), as taught by Murray, in order to determine high levels of IgE in serum that would indicate allergic diseases such as asthma, hay fever, and allergic rhinitis. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the step of detecting IgE, as taught by Murray, in the method of Dodge et al and Freytag et al, since Dodge et al and Freytag et al teach antibody targets, and IgE is one type of antibody.

23. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984) as applied to claim 1 above, and further in view of Rokugawa (US 4,623,618).

Dodge et al and Freytag et al references have been disclosed above, but fail to teach that the target molecules include a plurality of antibody molecules belonging to different subsclasses characterized by a difference in the hypervariable region of the antibody.

Rokugawa reference teaches quantifying each of IgG, IgA, and IgM (i.e. plurality of antibody molecules belonging to different subclasses), in order to diagnose infectious diseases, chronic hepatic disorder, immune diseases, or malignant tumors. See column 1, lines 30-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Dodge et al and Freytag et al with quantifying each of IgG, IgA, and IgM (i.e. plurality of antibody molecules belonging to different subclasses), as taught by Rokugawa, in order to diagnose infectious diseases, chronic hepatic disorder, immune diseases, or malignant tumors. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the step of detecting each of IgG, IgA, and IgM, as taught by Rokugawa, in the method of Dodge et al and Freytag et al, since Dodge et al and Freytag et al teach antibody targets, and IgG, IgA, and IgM are types of antibodies.

24. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984) as applied to claim 24 above, and further in view of Friend et al (US 5,173,293).

Dodge et al and Freytag et al references have been disclosed above, but fail to that the aptamer binds to a constant region of the antibody and wherein the immobilized ligand is the constant region of the antibody for removing unbound aptamer from the sample.

Friend et al reference teaches binding nucleic acids to the Fc region of an antibody, in order to providing coupling to an antibody without interfering with the binding of the antibody to another embodiment. See column 2, lines 54-61.

It would have been obvious to one ordinary skill in the art at the time of the invention to modify the method of Dodge et al and Freytag et al with the step of binding nucleic acids to the Fc region of an antibody, as taught by Friend et al, in order to providing coupling to an antibody without interfering with the binding of the antibody to another embodiment. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including Fc region binding of nucleic acids to antibodies, as taught by Friend et al, in the method of Dodge et al and Freytag et al, since Dodge et al and Freytag et al teach nucleic acid binding to antibodies, and the Fc region binding taught by Friend et al is one technique of binding nucleic acids to antibodies.

25. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984) as applied to claim 24 above, and further in view of Chandler et al (US 4,769,216).

Dodge et al and Freytag et al references have been disclosed above, but fail to that the second sample is divided into a plurality of aliquots.

Chandler et al reference teaches determining the presence of antibodies in a sample using a plurality of capillary elements, each with antigenic substances attached

to an internal surface and means for causing fluids to pass simultaneously through said capillary elements (i.e. divided into a plurality of aliquots), in order to screen a single sample (i.e. second sample) against a number of known antigen substances in a single test sequence. See column 2, lines 5-14 and 59-67.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Dodge et al and Freytag et al with the step of determining the presence of antibodies in a sample using a plurality of capillary elements, each with antigenic substances attached to an internal surface and means for causing fluids to pass simultaneously through said capillary elements (i.e. divided into a plurality of aliquots), as taught by Chandler et al, in order to screen a single sample (i.e. second sample) against a number of known antigen substances in a single test sequence. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in passing a single sample through multiple capillary elements simultaneously, as taught by Chandler et al, in the method of Dodge et al and Freytag et al, since Dodge et al and Freytag et al teach samples with antibody targets, and the capillary elements of Chandler et al are capable of retaining antibodies in samples.

26. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984) as applied to claim 24 above, and further in view of Chandler et al

(US 4,769,216) as applied to claim 29 above, and further in view of Dawson (US 4,943,525) and Michelson et al (US 5,246,832).

Dodge et al, Freytag et al, and Chandler et al references have been disclosed above, Chandler et al especially teaching means for causing fluids to pass simultaneously through capillary elements, each capillary element with antigenic different substances attached to an internal surface (i.e. contacting a plurality of aliquots of the second sample with an immobilized ligand wherein the ligand is immobilized to multiple substrates contained in a separate chamber, each immobilized ligand having a specificity). See column 2, lines 5-14 and 59-67.

However, Dodge et al, Freytag et al, and Chandler et al references fail to teach that each immobilized ligand is specific for an antibody with a different hypervariable site, and fail to teach the steps of recovering a third sample containing the aptamer bound to target molecules excluding the antibody bound to immobilized ligand, assaying the aptamer concentration in the third sample using the quantitative replicative procedure, so as to determine a difference in an amount of aptamer in the second sample and the third sample, and obtaining a measure of the antibody with the hypervariable region in the first sample from the difference.

Dawson reference teaches detecting both IgM and IgG antibodies to HIV (i.e. specific for an antibody with different hypervariable sites), in order to determine antibodies that can be detected at different time periods of exposure. See column 2, lines 18-36.

Michelson et al reference teaches performing parallel assays with subtraction of data from binding of IgM or IgG, in order to negate background binding. See column 5, lines 50-59.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Dodge et al, Freytag et al, and Chandler et al with the step of detecting both IgM and IgG antibodies to HIV (i.e. specific for an antibody with different hypervariable sites), as taught by Dawson, in order to determine antibodies that can be detected at different time periods of exposure, and with the step of performing parallel assays with subtraction of data from binding of IgM or IgG, as taught by Michelson et al, in order to negate background binding. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the steps of Dawson and Michelson et al, in the method of Dodge et al, Freytag et al, and Chandler et al, since Dodge et al, Freytag et al, and Chandler et al teach binding of antibody targets, and the steps of Dawson and Michelson et al involve binding of IgG or IgM, which are types of antibodies.

With regards to claim 32, Freytag et al teach antigen analogue (i.e. ligand is a specific antigen), as stated above.

27. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dodge et al (US 2002/0051974) in view of Freytag et al (Clinical Chemistry, vol. 30, no. 3, pp. 417-420, 1984) as applied to claim 24 above, and further in view of Chandler et al (US 4,769,216) as applied to claim 29 above, and further in view of Dawson (US 4,943,525)

and Michelson et al (US 5,246,832) as applied to claim 30 above, and further in view of Murray (US 3,957,436).

Dodge et al, Freytag et al, Chandler et al, Dawson, and Michelson et al have been disclosed above, but fail to teach that the antibody is IgE.

Murray reference teaches detecting IgE, in order to determine high levels of IgE in serum that would indicate allergic diseases such as asthma, hay fever, and allergic rhinitis. See column 3, lines 14-20.

It would have been obvious to modify the method of Dodge et al, Freytag et al, Chandler et al, Dawson, and Michelson et al with detecting IgE, as taught by Murray, in order to determine high levels of IgE in serum that would indicate allergic diseases such as asthma, hay fever, and allergic rhinitis. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the step of detecting IgE, as taught by Murray, in the method of Dodge et al, Freytag et al, Chandler et al, Dawson, and Michelson et al, since Dodge et al, Freytag et al, Chandler et al, Dawson, and Michelson et al teach antibody targets, and IgE is one type of antibody.

Response to Arguments

28. Applicant's arguments with respect to claims 1-34 and 45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

29. No claims are allowed.

30. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure:

Polito et al (US 4,081,246) teach solid phase column immunoassays for separating free from unbound fractions.

Freytag et al (US 4,517,303) teach a method for separating free antibody from analyte-antibody complex using an affinity column.

Cole et al (US 5,674,727) teach a subtractive substrate assay comprised of two separate specific binding assays.

Gold et al (US 5,567,588) teach the SELEX method for identifying nucleic acid ligands with high affinity for a target.

Cubbicciotti (US 6,287,765 B1) teach real-time PCR amplification and sequencing of aptamers.

Drolet et al (Nature Biotechnology, vol. 14, pp. 1021-1025, 1996) teach an enzyme-linked oligonucleotide assay with nucleic acids prepared from SELEX.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
Art Unit 1641

LYL

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/12/05